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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,505	11/05/2003	Shunji Natsuka	022219-000120US	9880

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EXAMINER	
KIM, TAEYOON	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
11/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,505	NATSUKA ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-38* is/are pending in the application.

4a) Of the above claim(s) *27-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Upon the further consideration of the instant application, the examiner decided to reopen the case. Therefore, the finality of the previous office action is withdrawn.

Response to Amendment

The declaration filed on 10/27/2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Seed et al. reference.

The declaration is defective because not all inventors signed the declaration. See M.P.E.P. §715.04 (B).

According to the declaration, co-inventors, Kevin Gersten and Shunji Natsuka, are also inventors for the claims under rejection (i.e. claims 37 and 38). Therefore, the declaration requires the signatures from these two co-inventors.

Although the evidence provided along with the declaration is sufficient to prove that applicant possessed the gene encoding Fuc-TVII enzyme in the 104 phage, and sequenced the gene using primers shown in the Exhibits, prior to the reference filing date (June 7, 1995), but it is still insufficient to prove that applicant actually possessed the enzyme per se, synthesized from the gene in the applicant's possession, prior to the filing date of the Seed et al. reference.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 37 and 38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The current claims are drawn to a

murine Fuc-TVII enzyme, which is naturally expressed in a mouse, and thus, the claimed invention does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter).

A naturally present Fuc-TVII gene encoding Fuc-TVII would comprise the catalytic domain identical to a polynucleotide amplified by the two primers (SEQ ID NOs: 3 and 4).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by a mouse in light of Seed et al. (US. 5,858,752).

Claims 37 and 38 are drawn to a murine Fuc-TVII enzyme.

The current claims read on a mouse. Since Seed et al. teach that a mouse carries the Fuc-TVII enzyme, it is an inherent property of a mouse to have a Fuc-TVII enzyme.

M.P.E.P. §2112 states that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. *v.* Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir.

1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re* Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re* Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Therefore, a holding of anticipation is clearly required.

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seed et al. (US 5,858,752) in view of Sasaki et al. (1994, J. Biol. Chem. 269:14730-14737).

Claims 37 and 38 are drawn to a murine Fuc-TVII enzyme comprising a catalytic domain encoded by a segment identical to a polynucleotide amplified by SEQ ID NO:3

and SEQ ID NO:4 (claim 37); and the catalytic domain consisting of residue 2194 to 3085 of SEQ ID NO:1 (claim 38).

Seed et al. teach a murine Fuc-TVII enzyme, encoded from a murine Fuc-TVII cDNA, and any analog or fragment thereof (column 16, lines 34-37).

Although Seed et al. do not particularly teach a catalytic domain of a murine Fuc-TVII enzyme, the fragments of a murine Fuc-TVII of Seed et al. comprise a fragment consisting of the catalytic domain of a murine Fuc-TVII enzyme. A person of ordinary skill in the art would deduce the sequence of the catalytic domain of a murine Fuc-TVII enzyme based from the catalytic domain of a human Fuc-TVII enzyme taught by Sasaki et al. (see Abstract).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to synthesize a murine Fuc-TVII enzyme of Seed et al. comprising a catalytic domain using a recombinant DNA technology based on the catalytic domain of a human Fuc-TVII of Sasaki et al.

The skilled artisan would have been motivated to make such a modification because the catalytic domain of the enzyme is a minimum requirement for the function of enzymatic activity. Therefore, a person of ordinary skill in the art would have been synthesized a murine Fuc-TVII enzyme comprising at least a catalytic domain of the enzyme by deducing the sequence of a murine Fuc-TVII based on a human sequence of Sasaki et al.

The person of ordinary skill in the art would have had a reasonable expectation of success in identifying a catalytic domain of a murine Fuc-TVII enzyme and generate

a murine Fuc-TVII enzyme comprising a catalytic domain because it was successfully carried out by Sasaki et al. with human Fuc-TVII enzyme.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 9:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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